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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/021,421	02/10/1998	RUSSEL T. JORDAN	399037	4431

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/021,421	JORDAN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,14-21,34-36 and 39-50* is/are pending in the application.

4a) Of the above claim(s) *7 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14-21,34-36,39-43 and 45-50* is/are rejected.

7)☒ Claim(s) *2-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 10/17/2006 has been entered.

Status of the Claims

Claims 1-7, 14-21, 34-36, and 39-50 are currently pending and are the subject of this Office Action. Claims 8-13, 22-33, 37-38 and 51-52 have been cancelled and claims 19 and 40-43 are currently amended. Claims 7 and 44 are withdrawn from consideration as being drawn to non-elected subject matter (please see discussion below). This is the first Office Action on the merits of the claims following a request for continued examination.

Election/Restrictions

Claims 7 and 44 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/10/2000. In the Restriction Requirement mailed 7/7/2000, examiner submitted that claims 1-22 and 23-33 were drawn to patentably distinct inventions (*i.e.* a composition and a method of using said composition). Applicants elected, with traverse, claims 1-22, drawn to a composition, in the reply filed 8/10/2000. Applicants amended claim 7 in the reply filed 12/29/2000 and

added claim 44 in the reply filed 10/26/2004. Both claims recite a composition of claim 1 (Claim 7) or claim 39 (claim 44) "in combination with necrotic tissue from a lesion of said group produced by the action of said composition upon the lesion". Examiner respectfully submits that instant claims 7and 44 are drawn to a method of using the compositions of claims 1 and 39, respectively. The "composition" of claims 7 and 44 directly results from the administration of the composition of claims 1 and 39 to a lesion and therefore requires a method step (*i.e.* administration of the composition to a lesion). Therefore, claims 7 and 44 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112 – First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14-21, 34-36, 47 and 50 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The instant claims recite compositions comprising "an escharotic chelatable metal agent" (*e.g.* Claim 1). There is insufficient written description in the specification so as to reasonably convey applicants had possession of the claimed invention at the time the application was filed.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

While the specification describes species of the instantly claimed "escharotic chelatable metal agent" (*e.g.* copper, iron, manganese, molybdenum, cobalt, and zinc) (page 4, lines 1-3), it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by "an escharotic chelatable metal agent". Aside from the specific agents recited in the specification and discussed *supra*, the disclosure does not name or describe any other metal agents. The examples are limited to specific combinations comprising zinc chloride and nordihydroguiaretic acid. As such, it is not clear that applicants had possession of the entire scope of the claimed invention as recited in the instant claims at the time the invention was made.

Further, the claims are drawn to compositions comprising "penetrants" and "antioxidants". These agents, as described in the specification, are drawn to a genus of active agents that are defined only by biological activity. Only a few species of the claimed agents are recited in the specification ("penetrant[s]", *e.g.* lecithan and DMSO, page 4, lines 8-9 and "antioxidant[s]", *e.g.* nordihydroguiaretic acid and ascorbic acid, page 4, lines 15-21).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of the complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present is that an agent acts as a penetrant or antioxidant. There is no description of structural characteristics that are required to retain biological activity. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath, Inc. v. Mahurkar, 19USPQ2d 111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed *supra*, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of penetrant and antioxidant, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or synthesizing it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only compositions comprising lecithan and/or DMSO as the penetrant and nordihydroguiaretic acid and/or ascorbic acid as the antioxidant, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. § 112, first paragraph.

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18, 39-43 and 45-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 recite the limitation "said penetrant" in line 1 of each respective claim. There is insufficient antecedent basis for this limitation in the claims.

Claim 39 recites the limitation wherein zinc chloride is present in a concentration of "at least five percent by weight of the composition and less than an amount that produces an eschar in healthy mammalian tissues." This limitation is indefinite because the upper concentration of zinc chloride is not readily apparent (*i.e.* is this 10%, 20%, 30%, etc.). It is not clear what concentration of zinc chloride will not produce an eschar in healthy mammalian tissue and the specification does not define such a concentration or provide one skilled in the art with the direction or guidance necessary to determine such a concentration. Claims dependent from claim 39 are included in this rejection.

Claims 48 and 49 recite the limitation "the penetrant" in line 2 of each respective claim. There is insufficient antecedent basis for this limitation in the claims.

Response to Arguments

Applicant's arguments, see pages 6-7 of response, filed 10/17/2006, with respect to the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) have been fully considered and are persuasive. The 35 U.S.C. § 102(b) rejection of claims 1 and 2 has been withdrawn.

The terminal disclaimer filed 10/17/2006 is sufficient to overcome the Obviousness-Type Double Patenting rejection of claims 1-7, 14-21, 34-36 and 39-50 over claims 1-25 of co-pending application no. 10/247,161 (now U.S. Patent No. 7,060,696). The double patenting rejection has been withdrawn.

Allowable Subject Matter

Claims 2-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1, 14-21, 34-36, 39-43 and 45-50 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

October 23, 2006

Ardin H. Marschel 10/29/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER